# Notice of References Cited Application/Control No. 10/527,355 Applicant(s)/Patent Under Reexamination NUNOYA ET AL. Examiner Patrick Stafford Art Unit Page 1 of 1

### **U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	Α	US-6,501,776	12-2002	Numai, Takahiro	372/45.01
*	В	US-4,583,227	04-1986	Kirkby, Paul A.	372/32 .
*	С	US-6,580,740	06-2003	Funabashi et al.	372/50.22
*	D	US-5,719,974	02-1998	Kashyap, Raman	385/37
*	E	US-5,155,737	10-1992	ikeda et al.	372/50.11
	F	US-			
	G	US-			
	Н	US-			
	_	US-			
	J	US-			
	К	US-			
	د	US-		•	
	М	US-			

### **FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	Ν					
	0					
	Р		,			
	Q					
	R					
	s	-				
	Т					

## **NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	٧	
	w	
	x	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Please amend page 20, line 1 as follows:

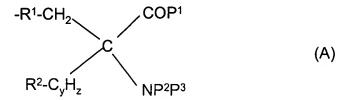
# Claims What is claimed is:

This listing of claims will replace all prior versions, and listings, of claims in the application:

# **Listing of Claims:**

1. (Original) A process for the production of an <sup>18</sup>F-labelled tracer which comprises treatment of a solid support-bound precursor of formula (I):

wherein the TRACER is of formula (A):



wherein  $P^1$  is hydroxy or a protecting group,  $P^2$  and  $P^3$  are independently hydrogen or a protecting group,  $R^1$  is a bond, -CH=CH-, or together with  $R^2$  forms  $R^3$ ;

$$R^3$$
 is  $-(CH)_j-C_mH_n-CH_q$ 

 $R^2$  is hydrogen or together with  $R^1$  forms  $R^3$ ;

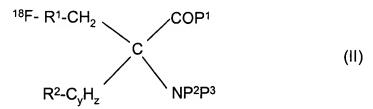
such that

$$-R^3$$
  $C$   $COP^1$   $C_yH_z$   $NP^2P^3$ 

is formed

wherein x is 0 or 1; y is 1 or 2; z is 1, 2, 3, or 4 and z>y if y is 2; q is 1 or 0 if n is 1 and j is 0; n is 1 or 2, but 0 if m is 0; m is 0 or 1; and j is 0 or 1;

with <sup>18</sup>F to produce the labelled tracer of formula (II)



wherein  $R^1$ ,  $R^2$ , y, z,  $P^1$ ,  $P^2$  and  $P^3$  are as defined for the compound of formula (I), optionally followed by

- (i) removal of excess <sup>18</sup>F<sup>-</sup>, for example by ion-exchange chromatography; and/or
- (ii) removal of any protecting groups; and/or
- (iii) removal of organic solvent; and/or
- (iv) formulation of the resultant compound of formula (II) as an aqueous solution
- 2. (Original) A process for the production of an  $^{18}$ F-labelled tracer according to claim 1 wherein  $R^1$  and  $R^2$  form the group  $R^3$ .
- 3. (Currently amended) A process for the production of an  $^{18}$ F-labelled tracer according to claim 1 or 2 wherein  $R^1$  and  $R^2$  form the group  $R^3$  and x is 0, y is 1, z is 2, q is 1, m is 0 and j is 0.
- 4. (Currently amended) A process according to any one of claims 1 to 3 claim 1 for the production of [<sup>18</sup>F]-1-amino-3-fluorocyclobutane-1-carboxylic acid ([<sup>18</sup>F]-FACBC) which comprises treatment of a solid support-bound precursor of formula (Ia):

wherein  $P^{2a}$  and  $P^{3a}$  are each independently hydrogen or a protecting group, and  $P^{1a}$  is hydroxyl or a carboxylic acid protecting group;

with <sup>18</sup>F to produce the labelled tracer of formula (IIa)

wherein P<sup>1a</sup>, P<sup>2a</sup>, and P<sup>3a</sup> are each as defined in Formula (Ia); optionally followed by

- (i) removal of excess <sup>18</sup>F<sup>-</sup>, for example by ion-exchange chromatography; and/or
- (ii) removal of the protecting groups; and/or
- (iii) removal of organic solvent; and/or
- (iv) formulation of the resultant compound of formula (IIa) as an aqueous solution.
- 5. (Original) A process according to claim 4 wherein the LINKER in the compound of formula (Ia) is

wherein k is an integer of 0 to 3, n is an integer of 1 to 16, and  $R^L$  is hydrogen or  $C_{1-6}$  alkyl.

6. (Currently amended) A process according to claim 4 or 5 in which  $P^{1a}$  is  $C_{1-6}$ alkoxy,  $P^{2a}$  is hydrogen or  $C_{1-6}$ alkoxycarbonyl, and  $P^{3a}$  is  $C_{1-6}$ alkoxycarbonyl.

- 7. (Currently amended) A process for the production of a <sup>18</sup>F-labelled tracer of formula (II) or (Ha), according to any one of claims 1 to 6 claim 1, for use in PET.
- 8. (Original) A compound of formula (I)

wherein the TRACER is of formula (A):

$$-R^{1}-CH_{2}$$

$$C$$

$$COP^{1}$$

$$R^{2}-C_{y}H_{z}$$

$$NP^{2}P^{3}$$
(A)

wherein  $P^1$  is hydroxy or a protecting group,  $P^2$  and  $P^3$  are independently hydrogen or a protecting group,  $R^1$  is a bond, -CH=CH-, or together with  $R^2$  forms  $R^3$ ;

$$R^3$$
 is -(CH)<sub>j</sub>-C<sub>m</sub>H<sub>n</sub>-CH<sub>q</sub>  $<$  (CH<sub>2</sub>)<sub>x</sub>-

R<sup>2</sup> is hydrogen or together with R<sup>1</sup> forms R<sup>3</sup>;

such that

$$-R^3$$
  $C$   $C_yH_z$   $C^{OP^1}$ 

is formed

wherein x is 0 or 1; y is 1 or 2; z is 1, 2, 3, or 4 and z>y if y is 2; q is 1 or 0 if n is 1 and j is 0; n is 1 or 2, but 0 if m is 0; m is 0 or 1; and j is 0 or 1.

# 9. (Original) A compound of formula (Ia):

wherein  $P^{2a}$  and  $P^{3a}$  are each independently hydrogen or a protecting group, and  $P^{1a}$  is hydroxyl or a protecting group.

10. (Currently amended) A compound according to claim 8 or 9 in which the LINKER is

wherein k is an integer of 0 to 3, n is an integer of 1 to 16, and  $R^L$  is hydrogen or  $C_{1-6}$  alkyl.

- 11. (Currently amended) A compound according to any one of claims 8 to 10 claim 8, in which  $P^{1a}$  is  $C_{1-6}$ alkoxy,  $P^{2a}$  is hydrogen or  $C_{1-6}$ alkoxycarbonyl, and  $P^{3a}$  is  $C_{1-6}$ alkoxycarbonyl.
- 12. (Currently amended) A radiopharmaceutical kit for the preparation of an <sup>18</sup>F-labelled tracer for use in PET, which comprises:
- (i) a vessel containing a compound of formula (I) or (Ia) as defined in any one of claims 1 to 6 claim1; and
- (ii) means for eluting the vessel with a source of <sup>18</sup>F<sup>-</sup>;
- (iii) an ion-exchange cartridge for removal of excess <sup>18</sup>F<sup>-</sup>; and optionally
- (iv) a cartridge for solid-phase deprotection of the resultant product of formula (II) or (IIa) as defined in any one of claims 1-to 6 claim1.

- 13. (Currently amended) A cartridge for a radiopharmaceutical kit for the preparation of an <sup>18</sup>F-labelled tracer for use in PET which comprises:
- (i) a vessel containing a compound of formula (I) or (Ia) as defined in any one of claims

  1 to 6 claim 1; and
- (ii) means for eluting the vessel with a source of <sup>18</sup>F<sup>-</sup>.
- 14. (Currently amended) A method for obtaining a diagnostic PET image which comprises the step of using a radiopharmaceutical kit according to claim 12 or a cartridge for a radiopharmaceutical kit according to claim 13.
- 15. (New) A method for obtaining a diagnostic PET image which comprises the step of using a cartridge for a radiopharmaceutical kit according to claim 13.